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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,322	04/02/2001	Matthew Marton	9301-136	8604
20583	7590	12/28/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			DEJONG, ERIC S	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 12/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,322

Applicant(s)

MARTON ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 64-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 12-21 and 64-74 is/are allowed.
- 6) ☒ Claim(s) 11 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Due to the indication of allowability the species election is withdrawn regarding claims 2-7 and examination is extended to include all species within 1-10 as set forth in the Office action, mailed 12/12/2002, within the elected Group I therein, which was elected by in applicants', filed 2/3/2003.

Claim Rejections - 35 USC § 101

The rejection of claims 1, 11, and 64-74 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of arguments presented by applicants.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11 and 22 are rejected under 35 U.S.C. 102(b) and 102(e)(2) as being anticipated by Goldenberg. This rejection is maintained and reiterated from the previous Office action.

The instant claims are drawn to a method for evaluating specificity of a drug comprising comparing activity of a drug against its target pathway and against at least one of its off-target pathways in a biological sample. Said activities are based on measurements of a plurality of cellular constituents and comprise calculating a specificity index according to a recited formula.

Goldenberg discloses the detection and treatment of infections via targeting diagnostic or therapeutic agents in the title and abstract. A variety of measurement methods are describes in column 8, line 52 through column 16, line 4, including MRI imaging, immunostaining, radiolabeling, etc. wherein various antibiotics are imaged as binding to targeted sites vs. non-targeted sites. The goal is to produce a therapeutic index which is evaluated as disclosed in column 3, lines 41-58, wherein a ratio of target to non-target localization is disclosed. These measurements and the resultant ratio evaluation anticipates such measurements and specificity ratio for at least $n=1$ as set forth in instant claims 11 and 22.

Response to Arguments

Applicant's arguments filed 09/15/2005 have been fully considered but they are not persuasive.

Applicants argue that Goldenberg does not teach activity of a drug against its target pathway in a biological sample and activity of said drug against at least one of its off-target pathways in said biological sample. Applicants further argue that amount of binding to a target (or non-target) does not teach an activity based on measurements of a plurality of cellular constituents and that Goldenberg's ratio measures the specificity of delivery (citing page 4, lines 9-16 and page 7, line 26-29 of the instant specification for support).

In response, the Examiner points to page 21 lines 17-21 of applicants response which states:

"The activity of a drug on its target pathway represents the action of the drug on such influence networks of cellular constituents of the target pathway, and the activity of the drug against on one or more non-target pathways represents the action of the drug on such influence networks of cellular constituents of the non-target pathway".

In the case of Goldberg, "the action of the drug" that influence networks of cellular constituents is the binding activity of antibiotics to target and non-target sites. As such, and contrary to applicants argument, the activity of the antibiotics disclosed in Goldenberg is represented by the specific binding of said antibiotics to target and non-target sites in a biological system, which is consonant with teachings of the instant disclosure. Further, upon review of the instant specification, no explicit definition has been provided that would exclude an embodiment wherein activity and specificity of drug binding is relied upon in the claimed steps of evaluation and comparison. Also, the instant claims do not recite any limitation that excludes the evaluation and comparison

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of drug binding activity to target and non-target sites. Therefore applicants arguments are not found persuasive.

Applicants further argue that Goldenberg does not teach determining the specificity of a drug by calculating a ratio of D_{target} to $D_{\text{off-target}}$.

In response, the Examiner reiterates from the above rejection that Goldenberg produce a therapeutic index which is evaluated as disclosed in column 3, lines 41-58, wherein a ratio of target to non-target localization is determined. These measurements and the resultant ratio evaluation anticipates the limitation of calculating a specificity index as set forth in instant claims 11 and 22, wherein the number of off-target pathways is 1 (ie: $n=1$). Therefore applicants argument is not found persuasive.

Allowable Subject Matter

Claims 1-10, 12-21, and 64-74 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

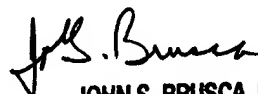
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contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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EDJ



 20 December 2005
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER